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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,193	08/28/2001	James E. Dahlberg	FORS-06613	6777
23535	7590	01/25/2005	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			AKHAVAN, RAMIN	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

1/25/05

Office Action Summary	Application No.	Applicant(s)	
	09/941,193	DAHLBERG ET AL.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 95-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 95-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a response filed, 09/23/2004. Claims 95-108 are pending and under consideration in this action. All objections/rejections not repeated herein are hereby withdrawn. As no new grounds of rejection are set forth, **this action is made FINAL.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. **Claim 95-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

This rejection was made previously and is repeated herein. A response to Applicant's arguments is set forth below.

Base claim 95 recites the term "system". There does not appear to be a specific definition for this term in the specification. It is unclear whether "system" is to be interpreted to mean that the claims are drawn to specific method steps or the claims are drawn to a way of using a particular product, or simply to a composition (e.g. a kit) comprising the recited nucleic acids. Therefore, the claims' metes and bounds are indefinite. For example, in claims drawn to a method comprising a number of action steps, there would eventually a particular outcome. The instant claims are vague and indefinite, so that it is unclear what outcome is intended.

Response to Arguments

Applicant's arguments have been considered but are not deemed persuasive. Base claim 95 has been amended to recite "A nucleic acid analysis system", in response to a rejection made under 35 U.S.C. § 112, second paragraph, with respect to the term "system". Applicant asserts that the term "system" is used throughout the specification and is used on numerous occasions as a general term that refers to a collection of components. (Remarks, p. 3, top). Applicant points to Table I of the specification as proof that term "system" is not vague and indefinite. (Specification, p. 5; Applicant also points to p. 40, line 245, but no such line exists).

However, the very table to which Applicant points, recites "Method" under which are the various systems to which Applicant refers. In fact, Table I and the corresponding passages in the specification further highlight the point that the term "system" implies that additional components or elements are necessary. Each of the processes that Table I recites encompasses a method, which incorporates various steps, components or elements. *Arguendo* if the term "system" in claim 95 is to be interpreted to be directed to a method (such as the methods referred to in Table I), then the claims would still be vague and indefinite because there are no action steps in claim 95.

Therefore it is unclear whether claim 95 is directed to a method or a composition. However, if the claim were to read, "A composition comprising" subpart a-d, then there would be no ambiguity. Alternatively, if the claim were to read "A method for nucleic acid analysis comprising" then there would be no ambiguity, but with the caveat that a method must contain action step(s).

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In sum, the amendment does not particularly and definitively claim the invention, but merely presents a modifier for the term "system", where the term "system" connotes that additional steps, components or elements are required. As it is unclear what these additional steps or components may be, and it is unclear whether the claims are directed to a method or compositions, the claims' metes and bounds remain indeterminable.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached between 8:30-5:00, Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 571-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636


GERRY LEFFERS
PRIMARY EXAMINER